

## REMARKS

### Rejections Under Section 112

Claims 1, 17 and 18 are rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite for a variety of reasons, each of which will be addressed below. These grounds of rejection are respectfully traversed.

The first ground of rejection is with respect to the phrase “without substantially denaturing.” The claim language has been changed to recite “while denaturing only a selected amount” of the PI2. The methodology disclosed in the application for the quantification of the target protein analytes is an HPLC assay of a liquid supernatant using a diode array detector set to 220 nm. One skilled in the art would recognize that this assay methodology is effective to determine whether or not a selected amount of the target analyte (PI2) has been denatured in terms of :

- a. No cleavage of amide bonds in the protein analyte, as this is necessary for detection at 220 nm;
- b. Solubility of the protein analyte so that it is present in the matrix after sample conditioning; and
- c. Conserved structure of the protein analyte in that HPLC identification requires consistent structure to determine the retention time.

One skilled in the art would understand that “while denaturing only a selected amount” of the PI2 in the context of the present application means that the PI2 would remain assayable by the disclosed HPLC assay. As such, the claim, as amended, is not indefinite and the rejection under Section 112, second paragraph, should be reconsidered and withdrawn.

The second ground of rejection under Section 112 is with respect to the phrase “to selectively affect purity and yield” in claims 1, 17 and 18. Claim 1 has been amended to add a specific range of temperatures (between 60° C and 90° C) and a specific time period (between 15 minutes and 90 minutes). In the specification, Table 3 demonstrates a variety of temperatures and times, along with associated overall purity outcomes from those examples. One of ordinary skill in the art would observe that increasing purity is achieved corresponding to increased temperature with process time held consistent, for example at 15 minutes. Similarly when temperature is held constant, i.e. 60 °C, purity increases as time is increased. Claims 17 and 18

have been amended to more particularly point out and distinctly claim this aspect of the present invention.

The specification thus teaches those of ordinary skill in the art how to achieve a variety of purity endpoints through adjustment of the conditions. No target endpoint is suggested, as the novel nature of the invention is the ability to control the purity, as opposed to having a directed objective to maximize or minimize the purity of the proteinase inhibitor II molecule. If purity is paramount, one skilled in the art can follow the disclosure of Table 3 and the specification relating thereto in order to adjust the temperature and time duration of the heating step in order to maximize purity. If, on the other hand, yield is paramount, one skilled in the art can follow the disclosure of Table 3 and the specification relating thereto in order to adjust the temperature and time duration of the heating step in order to maximize yield. Of course, the same disclosure can be followed to allow one skilled in the art to adjust the conditions to achieve combinations of purities and yields below the maximum of each.

The third ground of rejection under Section 112 relates to the phrase “removing denatured protein products”. It is believed that the change in language to “while denaturing only a selected amount” of the PI2 addresses this ground of rejection in that the PI2 is not longer arguably recited to be partially denatured; it is either denatured or not denatured and an assay for non-denatured PI2 is provided in the specification.

Reconsideration and withdrawal of the Section 112 rejections in view of the foregoing amendments and these remarks is respectfully requested. Since claims 17 and 18 were rejected only on the basis of Section 112 and not based on prior art, these claims are now in condition for allowance.

#### Rejections under Section 102(b)

Claims 1-4 and 10-12 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Ryan. Claim 1 has been amended as suggested by the Examiner to distinguish it from the Ryan reference. Reconsideration and withdrawal of the Section 102(b) rejection is respectfully requested.

### Rejections under Section 103(a)

Claims 1-7 and 8-10 (*sic*)<sup>1</sup> are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Ryan et al. in view of Borud in view of Pearce et al. in view of Bryant et al. This ground of rejection is traversed.

Claim 1 has been amended to positively recite that the extraction step is free of alcohol. This clearly distinguishes Ryan et al, Pearce et al., and Bryant et al., all of which require the use of alcohol in the extraction step. The method taught by Borud differs in several respects from the present methods, including importantly the use of a strong acid, namely hydrochloric acid, rather than the weaker organic acids recited in the present claims. The differences in the Borud methods result in the requirement that sulfur dioxide be added (and possibly that additional sulfite be added in the form of sodium sulfide) in order to achieve effective coagulation (denaturation) of the inactive proteins (paragraph bridging column 4 and 5). Borud, column 4, lines 31-37 teaches that: “The result of coagulation depends on ... concentration of sulfite in the potato juice...” The present invention teaches a method of extraction and purification that is sufficiently distinct from the Borud method such that no sulfite is required to obtain the purified extract.

The Examiner states, in the last paragraph on page 9, that: “It is clear that it is the temperature which denatures proteins, and not the length of time which the protein is subjected to the heat treatment.” This statement ignores the data presented in the present specification that demonstrates both a time and temperature dependence on the resulting PI2 purity. It also ignores the teachings of Borud wherein coagulation (denaturing) of the proteins is stated to be dependent on temperature, time of heat treatment, pH, and concentration of sulfite (column 4, lines 31-37). The heat stability of the various proteins in a potato composition as discussed in the prior art references, as well as the present application, is greatly dependent on the solution conditions of each composition. Ryan requires the presence of alcohol in the extraction step; Borud requires the presence of sulfite in the extraction step and in the coagulation step; Pearce requires alcohol in the extraction step; Bryant requires alcohol in the extraction step. The Examiner impermissibly picks and chooses reaction conditions from four different prior art references and applies them piecemeal to reject the present claims. None of the prior art references teaches or suggests that an extraction step in the absence of alcohol and use of an organic acid will allow

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<sup>1</sup> Claims 8 and 9 had previously been canceled; Applicant has treated this as a rejection of claims 1-7 and 10-16.

the extraction of PI2, much less that the reaction conditions can be selected either to prefer purity over yield, yield over purity, or intermediate combinations of purity and yield, as desired by one skilled in the art. Claim 1 is patentably distinct from any proper combination of the cited references and thus each of its dependent claims 2-7 and 10-16 are also patentable distinct. Reconsideration and withdrawal of the Section 103(a) rejection of claims 1-7 and 10-16 is respectfully requested.

The application has been amended to correct minor informalities, to further distinguish the application over the prior art, and to more particularly point out and distinctly claim the subject matter that Applicant regards as the invention so as to place the application, as a whole, into a prima facie condition for allowance. Great care has been taken to avoid the introduction of new subject matter into the application as a result of the foregoing modifications.

Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching which would lead one skilled in the relevant art to combine the references in a manner which would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

Based on the foregoing, Applicant respectfully submits that its claims 1-7 and 10-19, as amended, are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

Respectfully submitted,

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